CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050454	A. BUILDING _____ B. WING _____	09/24/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UCSF MEDICAL CENTER	505 PARNASSUS AVENUE, SAN FRANCISCO, CA 94122-0210 SAN FRANCISCO COUNTY

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	The following reflects the findings of the Department of Public Health during a Full Validation Survey. Representing the Department of Public Health: [redacted] Pharmaceutical Consultant [redacted] Pharmaceutical Consultant [redacted] Pharmaceutical Consultant [redacted] Medical Consultant [redacted] Health Facilities Evaluator Nurse [redacted] Health Facilities Evaluator Nurse [redacted] Health Facilities Evaluator Nurse [redacted] Dietician 1280.1(a) Health and Safety Code Section 1280 (a) If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation. 1280.1(c) Health and Safety Code Section 1280 (c) For purposes of this section " immediate jeopardy " means a situation in which the licensee' s noncompliance with one or more requirements of licensure has caused, or is likely to cause serious injury or death to the patient. TITLE 22 DIV5 CH1 ART3-70263(c)(1)(2) (c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least			

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	Continued From page 1 one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. (2) The committee shall be responsible for the development and maintenance of a formulary of drugs for use throughout the hospital. The above regulations are not met as evidenced by: Based on clinical record review of three patients (Patient 1, 2 and 3), document review, and interview of hospital staff, the hospital failed to ensure that policies and procedures were developed and/or implemented to ensure accurate administration of medications to Patient 2, and minimize adverse medication outcomes for Patient 1 and 3 as evidenced by the following: a. Patient 2 ' s medication administration record (MAR: used by nursing staff to guide the administration of medications to their patients) did not accurately reflect the physician orders which potentially exposed Patient 2 to the excessive effects of medications or deprived the patient of the			

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	Continued From page 2 benefit of medications therapy for those medications which did not appear on the MAR. b. Patient 1 received dose increases in fentanyl patch (a potent synthetic opiate narcotic manufactured in patch form that releases the medication in a controlled fashion and is indicated for the management of chronic pain in narcotic tolerant patients whose pain has not been manageable by other means) that were not in accordance with the manufacturer's dosing guidelines and as a result required treatment with a reversal agent, naloxone. c. Review of Patient 3 ' s clinical record on September 22, 2007 at 11:47 a.m. revealed the hospital failed to ensure that a possible adverse reaction to ondansetron (Zofran: used to treat nausea) had been entered onto the physician order sheets by a physician and had been documented on the cover of Patient 3 ' s clinical record, as required by a hospital policy and procedure, so that subsequent physicians and other staff such as pharmacists would be alerted to this reaction. As the reaction was not documented on the cover of the clinical record, a second physician prescribed ondansetron six days later potentially exposing Patient 3 to the drug a second time. Findings: 1. On 9/20/07 at 11:38 a.m., a review of Patient 2 ' s clinical medical record revealed the patient was status post heart transplant in June 2007 and diagnosed to be immunosuppressed (suppression			

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	Continued From page 3 of the immune system by drug use in order to prevent the rejection of grafts or transplants). A review of Patient 2 ' s Medication Administration Record (MAR) against the current physician orders revealed 9 medication order discrepancies out of a total of 30 medications. The following were the 9 discrepancies found, along with the medication order as written: a. Valgancyclovir (antifungal medication) - patient received 450mg twice a day as documented on the MAR. The current order in the chart was for 450mg daily. The patient received double the dose which could lead to adverse drug consequences. b. Magnesium Oxide (magnesium supplement) - patient received 800mg twice a day as documented on the MAR. The current order in the chart was for 800mg daily. The patient received double the dose which could lead to adverse drug consequences. c. Robaxin 500mg every 6 hours as needed for muscle spasm- this medication was listed on the MAR. There was no current order in the chart for the patient to receive this medication. d. Vicodin 1-2 tablets every 6 hours as needed for pain was ordered for the patient on September 18, 2007. This medication was not listed on the MAR so the nursing staff would not know the patient had an order for this medication when needed to treat his pain. e. Zofran 4mg IV every 6 hours as needed for			

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	Continued From page 4 nausea and vomiting was documented on the MAR. There was no current order in the chart for the patient to receive this medication. f. Bisacodyl suppositories 10mg rectally every 12 hours as needed for constipation was ordered on September 18, 2007. This medication was not listed on the MAR so the nursing staff would not know the patient had an order for this medication when needed for constipation. g. Clonidine (blood pressure medication) 0.3mg three times a day was ordered on September 18, 2007 with the following blood pressure monitoring parameters, i.e. hold if systolic blood pressure less than 80, pulse less than 55. These parameters were not transcribed on the MAR and the patient might receive this medication when it should have been held. h. Amlodipine (blood pressure medication) 10mg daily was ordered on September 18, 2007 with the following monitoring parameters, i.e. hold if systolic blood pressure less than 80. This parameter was written on the MAR as hold if systolic blood pressure less than 90. This incorrect parameter could prevent a needed dose from being given. i. Tylenol 650mg every 4 hours as needed for temperature greater than 38.5 or mild pain. According to the facilities plan of correction from a previous survey performed on June 27-29, 2007 and dated August 20, 2007, Tylenol orders should have a maximum daily dose included with each order. The MAR which should have reflected the complete			

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	Continued From page 5 physician order including parameters and maximum doses did not have this maximum daily dose documented. 2. On September 18, 2007 review of Patient 1 ' s clinical record revealed that on August 31, 2007, a physician ordered that a 25 micrograms per hour (mcg/hr) fentanyl patch be applied to Patient 1. Fentanyl is a potent synthetic opiate narcotic. One available dosage form is a patch that releases the medication at a controlled rate measured in mcg/hr. It is indicated for the treatment of chronic pain that is not adequately controlled by other means. On September 2, the dose was increased to a 50 mcg/hr patch. On September 3, 2007 the dose was increased to a 75 mcg/hr patch. On September 8, 2007 the dose was increased to a 100 mcg/hr patch. On September 9, 2007 the dose was increased to a 150 mcg/hr patch and on September 10 the dose was reduced to a 75 mcg/hr patch. Review of a physician ' s progress note in the electronic clinical record on September 18, 2007 at 4:21 p.m. revealed that on September 10, 2007 at 11:32 a.m. a physician noted that the fentanyl patch had been " increased considerably " yesterday-based on large amount of PRN (as needed) Roxanol (a liquid morphine preparation) use. While writing note, nurse contacted me that RR (respiratory rate: normal rate for an adult, per the Medline Plus Medical Encyclopedia, is 8 to 16 breaths per minute) 7-8 (breaths per minute). Will give Narcan 0.1mg IV X1 (one 0.1 mg dose of the narcotic reversal agent Narcan), hold all PRN po			

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	Continued From page 6 (oral) Roxanol this afternoon and change fentanyl patch back to 75 mcg TD (transdermal: in other words via the patch) q72 (every 72 hours). Will also check RR q1H (every one hour) throughout the afternoon-dose given yesterday around 4 p.m. " On September 18, 2007 at 4:05 p.m. review of the manufacturer ' s package labeling for the fentanyl patch in the Mt. Zion Campus pharmacy revealed the manufacturer documented that (1) each patch could be worn for 72 hours (2) that the initial patch dose could be increased after three days based on supplemental doses of narcotics administered during the three day period. The product labeling documented that after increasing the fentanyl patch dose it may take up to six days to reach a new equilibrium on this new dose and, therefore, patients should wear the new higher dose through two applications (of 72 hours each) before any further increase in dosage via the patch was made. During an interview of Staff Member 1 in the Mt. Zion Campus pharmacy on September 18, 2007, he could provide no evidence that supported deviation from the titration schedule as documented by the manufacturer in the product labeling or that pharmacy staff had questioned the dose increase as ordered. 3. On September 22, 2007 at 11:47 a.m., review of Patient 3 ' s clinical record at the Mt. Zion Campus revealed that the Adult Admit/Transfer Orders dated September 11, 2007 documented that Patient 3 had no known allergies. The clinical record contained two pre-printed orders for patient			

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	Continued From page 7 controlled analgesia (PCA: allows the patient to self administer pain medication within physician established parameters while under nursing monitoring) dated September 11th at 7:10 a.m. and September 18th at 12:25 a.m. respectively. Physician 2 had signed the second set of PCA orders. Both pre-printed PCA order sets also had a space in which any allergies a patient had could be added by the prescribing physician. The prescribing physician had written " NKDA " (no known drug allergies) in the allergy space on both PCA orders sets. Both PCA orders sets pre-printed orders for ondansetron (Zofran: used to treat nausea) to be given intravenously every 6 hours as needed for nausea. Because the orders had been checked on both order sets, the physician had indicated that the patient was to receive this drug as needed to control any nausea the patient may have while on PCA. On September 12, 2007 at 1:25 p.m. Physician 1 discontinued the Zofran (from the first order set). On September 18, 2007, at 9:05 a.m., Physician 1 discontinued Zofran again (from the second order set) with instructions to " See AOS " (antibiotic order sheet). Review of the antibiotic order sheet revealed that it too had a space in which the patient ' s allergies, if any, could be filled in and Zofran had been filled in the space. Review of the medication administration record (MAR: used to document the date and time a dose of medication was administered to a resident and the identity of the person administering the dose) revealed that this patient received one 4 mg dose of ondansetron on September 11, 2007 at 7 p.m. All the MARs had a space in which the patient ' s			

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	Continued From page 8 allergies, if any, could be written. All the MARs in Patient 3 ' s clinical record had " ondansetron " written in on this " Allergic to: " space. Other clinical records had been noted during the survey that had red bordered allergy stickers on the front cover of the clinical record on which staff had written in the allergies for those patients but Patient 3 ' s clinical record had no such sticker on the cover. During an interview of Patient 3 on September 22, 2007 at 12:45 p.m. in her room, she stated that one night she felt nauseated and requested Zofran (she only received one dose on September 11th as documented above). Soon after getting it, she felt numbness in her feet that over a period of 15 to 20 minutes moved up her body until her whole body including her face was involved. She also reported that she had difficulty breathing and that her fingers felt stiff. She reported that she had had the same reaction, only more severe, during a car trip a couple of months prior to her hospitalization. She stated she had that reaction after consuming two cans of a commercially available beverage, however she consumed the beverages at about 11 a.m. and later in the afternoon but did not have the reaction until about 8 that evening. She had an allergy alert bracelet on her arm listing ondansetron as a medication to which she was allergic and she reported this band had been put on her arm the day after the reaction. On September 22, 2007, at 1:15 p.m. during an interview of Physician 1 on Mt. Zion Campus, he stated that he wrote the orders to discontinue			

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	Continued From page 9 ondansetron on both September 12 and September 18, 2007. He stated that he had been called because the resident had complained of rigors (shaking). He was not sure if the patient had had an adverse reaction to ondansetron but after discussing the issue with the nursing staff, he decided to call this an " allergic " reaction. He stated that it would be prudent after a patient has had a reaction soon after getting a drug to discontinue it and to prevent the patient from getting it again unless the need was so great that a test dose would be attempted to see if the patient might tolerate the medication in question. He was notified by the nursing staff on September 18, 2007 that ondansetron had been prescribed to the patient with a documented allergy to the medication (this was documented on the MARs) and requested that he discontinue the medication which he did. He stated that he depended on the presence of an allergy sticker on the front of the clinical record as well as a review of the Adult Admit/Transfer Orders to determine a patient ' s allergy status. As this adverse reaction occurred after admission, caregivers would have to depend on an " allergy " sticker placed on the cover of this patient ' s clinical record with the offending medication filled in as the first line of prevention for the receipt of this medication. Review of Patient 3 ' s computerized medication profile in the Mt. Zion Campus pharmacy revealed that Zofran was listed as an allergy. When asked when it had been entered into the profile data base, Staff Member 3 determined that ondansetron had been entered into the allergy field on September 18,			

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	Continued From page 10 2007, seven days after the original incident and six days after ondansetron had been discontinued on September 12, 2007. On September 22, 2007 at 2:56 p.m. review of the policy and procedure entitled Allergy Identification revealed it stipulated that if allergies are identified during the course of a patient ' s hospital stay, the physician will document the allergy on the physician order sheet which will then be processed and sent to the pharmacy and other departments as necessary. It documented that nursing staff were to affix an allergy sticker on the clinical record cover and note the allergies on the sticker. On September 22, 2007 at 12:33 p.m. during an interview of Staff Member 4 on Mt. Zion Campus, she stated there should have been an allergy sticker on the cover of Patient 3 ' s clinical record (noting ondansetron as an " allergy ") and it was, in fact, not there. Other staff members who were present at the time of the interview of Staff Member 4 all agreed that while the reaction was not an allergic reaction (mediated by antibodies produced by the body after exposure to a foreign substance) it should be noted in allergy fields in and on the clinical record (and by extension, in the computerized pharmacy patient profile) in order to alert physician and other staff members that the patient had had such a reaction in the past. No evidence was provided that the Physician 1 had filled in this adverse reaction in the physician order sheet or that the pharmacy had been notified of this adverse reaction (until seven days after the index reaction) as required by the hospital policy and			

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	Continued From page 11 procedure. No allergy sticker had been placed on the cover of the clinical record at the time of the reaction which could have subsequently alerted Physician 2 about the " allergy " so that he could have taken that into consideration when he filled out the pre-printed PCA order set on September 18, 2007 when he ordered ondansetron for Patient 3 for a second time. The violations have caused or are likely to cause serious injury or death to the patients.			

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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.